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EXAMINER

HUNT, JENNIFER ELIZABETH

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/509,779

Applicant(s)

SUN, YI

Examiner

Jennifer E Hunt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 18-24, 27-31 and 33-37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 9, 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-8, 10-14, 17, 25, 26 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-17, 25-26, and 32 and further election of the species of SEQ ID NO:3 in Paper No. 12 is acknowledged. SEQ ID NO:3 was found to be free of the prior art and thus the search was extended to include all of the DNA species.
2. Claims 1-37 are pending in the application. Claims 18-24, 27-31, and 33-37 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-17, 25-26, and 32 are considered herein.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-2, 4-8, 10-14, 17, 25-26, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth below.
4. The term "substantially similar" in claims 1, 4, 5, 7, 10, 11, 25-26, and 32 is a relative term which renders the claims indefinite. The term "substantially similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, it is not clear how

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many changes, and what nature of changes would be permitted in a DNA sequence which meets the limitation of the claims.

5. The term "high stringency hybridization conditions" in claims 2, 4, 5, 8, 10, 11, 25-26, and 32 is a relative term which renders the claim indefinite. The term "high stringency hybridization conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Specifically, although a range of conditions is specified as preferable, there are no specific conditions set forth which clearly delineate the metes and bounds and thus it cannot be determined what would be considered high stringency and what would not.

6. Claims 5, 11, and 17 are unclear in the recitation of a "host cell comprising a host cell transfected...". It is not clear how a host cell can comprise a host cell transfected with..."

7. Claims 25, 26, and 32 are unclear in the recitation of a SAG gene, because the composition is given an arbitrary name. While the name itself may have some notion of activity of the protein, there is nothing in the claims which distinctly claims the protein. Others in the field may isolate the same SAG gene and give such and entirely different name. Applicant should particularly point out and distinctly claim SAG gene by claiming characteristics associated with the protein. Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what the protein is.

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8. Claims 25 and 26 are unclear in the recitation of "primers derived from". The metes and bounds of "derived from" cannot be determined. It is not clear what would be considered "derived from" and what would be considered a completely different composition altogether. Specifically, it is not clear how many changes or difference are permitted within a primer and still have it be considered derived from the claimed DNA sequences.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 6 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a requirement for deposit.

The specification lacks complete deposit information for the deposit of the host cells designated under ATCC accession numbers 98402, 98403, 98404, and 98405. While the specification provides enough information for one of skill in the art to produce cells with the same or similar properties as the host cells designated under ATCC accession numbers 98402, 98403, 98404, and 98405, reproduction of an identical host cell is an unpredictable event. Because it does not appear that the host cells designated under ATCC accession numbers 98402, 98403, 98404, and 98405

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are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because certain of the claims specially require the use of the host cells designated under ATCC accession numbers 98402, 98403, 98404, and 98405, a suitable deposit of these host cells for patent purposes is required or evidence must be provided that the host cells designated under ATCC accession numbers 98402, 98403, 98404, and 98405 is well known and readily available to the public.

Furthermore, unless the deposit was made at or before the time of filing, a declaration filed under the 37 C.F.R. 1/132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited host cells by their depository accession number, establish that the deposited host cells are the same as that described in the specification, and establish that the deposited host cells were in applicant's possession at the time of filing. See In re Lundak, 773 F.2d. 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985).

It is not clear from the disclosure that deposits of the host cells designated under ATCC accession numbers 98402, 98403, 98404, and 98405 meet all the criteria set forth in MPEP 608/01 (p)(C), items 1-3. Assurance of compliance may be in the form of a declaration or averment under oath. A suggested format for such a declaration or averment is outlined below:

#### SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

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2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.
6. States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.
7. Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.
8. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, and the complete taxonomic description.

As a possible means of completing the record, applicants may submit a copy of the deposit receipt.

11. Claims 1-2, 4-5, 7-8, 10-11, 25-26, and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are broadly drawn to a DNA of any size comprising a sequence that is substantially similar to, hybridize to, or are derived from SEQ ID NO:1 or 3. The claims are drawn to a DNA molecule of any size which is only defined by a small number of nucleic acid residues, hence the claims are drawn to nucleic acid sequences which minimally contain only portions of SEQ ID NO:1 or 3. Thus the claims are drawn to a large genus of molecules. In the case of small identified nucleic acid residues claimed with open language, the genus of the polynucleotides comprising a partial sequence encompasses a variety of subgenera with widely varying attributes. The specification discloses only the structural features of the polynucleotides of SEQ ID NO: 1 and 3. The specification lacks information to lead one of ordinary skill in the art to understand that the applicant had possession of the broadly claimed genus of polynucleotides at the time the instant application was filed. Applicant is referred to the guidelines for 112, first paragraph, published in the Official gazette and also available on [www.uspto.gov](http://www.uspto.gov).

12. Claims 1-2, 4-5, 7-8, 10-11, 25-26, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA comprising SEQ ID NO:1, 3, 11, 13, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, and 49, does not reasonably provide enablement for sequences which are substantially similar to, hybridize to, or are derived from SEQ ID NO:1 and 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining scope and enablement are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented in the specification, 3) the presence or absence of working examples, 4) the nature of the invention, 5) the state of the prior art, 6) the relative skill of those in the art, 7) the predictability of the unpredictability of the art, and 8) the breadth of the claims (see *Ex parte Forman*, 230 USPQ 546, BPAI, 1986).

The specification discloses only the DNA sequences of SEQ ID NO:1 and 3.

The claims are broadly drawn to sequences which are substantially similar to, hybridize to, or are derived from SEQ ID NO:1 and 3.

Thus the claimed sequences include a broad category of DNA molecules, including variants, fragments, and derivatives of the disclosed sequences, while the specification teaches only the sequences of SEQ ID NO: 1 and 3.

The unpredictability of DNA mutations, fragments, and variants is set forth below:

Bowie et al (*Science*, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of

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the protein is extremely complex. (col 1, p. 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (col 2, p. 1306). The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess et al ( J of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar et al (Molecular and Cellular Biology, 1988, 8:1247-1252) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein. In addition, Bork (Genome Research, 2000,10:398-400) clearly teaches the pitfalls associated with comparative sequence analysis for predicting protein function because of the known error margins for high-throughput computational methods. Bork specifically teaches that computational sequence analysis is far from perfect, despite the fact that sequencing itself is highly automated and accurate (p. 398, col

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1). One of the reasons for the inaccuracy is that the quality of data in public sequence databases is still insufficient. This is particularly true for data on protein function. Protein function is context dependent, and both molecular and cellular aspects have to be considered (p. 398, col 2). Conclusions from the comparison analysis are often stretched with regard to protein products (p. 398, col 3).

Therefore, due to the breadth of the claims, the lack of guidance in the disclosure, and the unpredictability of the art as set forth above, one of skill in the art would not be enabled to make to use the invention as broadly claimed.

### ***Conclusion***

13. Claims 3, 9, 15, and 16 are allowed. Claims 1-2, 4-8, 10-14, 17, 25-26, and 32 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached on Monday-Friday, 6-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Jennifer E Hunt  
Examiner  
Art Unit 1642

jeh  
January 6, 2002

  
SHEELA HUFF  
PRIMARY EXAMINER